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A5T TSD TSE TED T102 T11X
PLB FDX

(56) Documents cited
GB 2179322 A GB 2063075 A GB 1383781 A
GB 1382282 A GB 1217315 A WO 87/05913 A
US 4790679 A

(58) Field of search
UK CL (Edition K) A5T TSC TSD TSS TED, PLB
G01F
INT CL* A61M

(54) Inhalation device

(57) An inhalation device for administration of aerosolised medicament to the respiratory system of a patient, in which the inhalation device accommodates a reservoir of medicament which comprises information relating to the medicament and the inhalation device includes sensing means capable of detecting said information and means to display or use the detected information. Suitable sensing means include electrical contacts which mate with corresponding coded electrical contacts in the form of wipers, spring loaded contacts or phalecdats on the medicament reservoir in a similar manner to the DX-coding arrangement in cameras.

GB 2 262 452 A

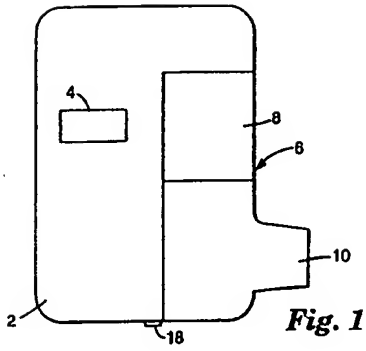

Fig. 1

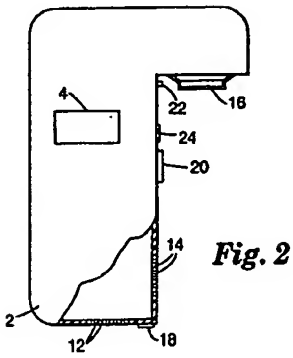

Fig. 2

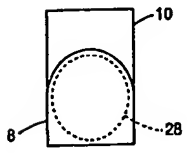

Fig. 3a

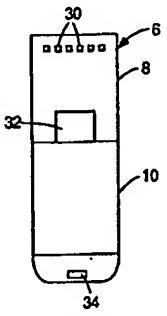

Fig. 3b

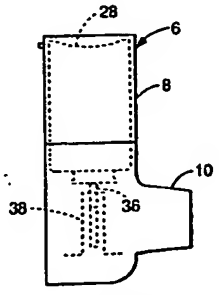

Fig. 3c

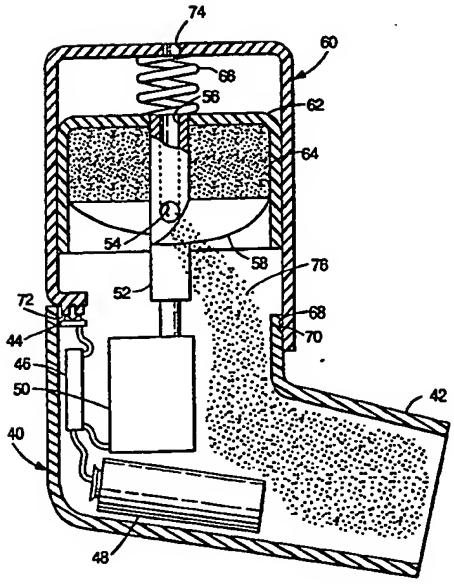

Fig. 4

INHALATION DEVICE

This invention relates to an inhalation device for administration of medicament in the form of aerosolised solid particles or droplets of liquid or suspension.

Asthma and other respiratory diseases have long been treated by the inhalation of appropriate medicament. For many years the two most widely used and convenient choices of treatment have been the inhalation of medicament from a drug solution or suspension in a metered dose pressurised inhaler (MDI), or inhalation of powdered drug generally admixed with an excipient, from a dry powder inhaler (DPI).

Inhalation activatable dispensers for use with aerosol containers which contain medicament and are pressurised with liquid propellants and are equipped with a metering valve through which a plurality of metered doses may be dispensed are known, their general purpose being to afford proper co-ordination of the dispensing of a dose of medicament with the inhalation of the patient thereby allowing the maximum proportion of the dose of medicament to be drawn into the patient's bronchial passages. Examples of such dispensers are described in British Patent Specification Nos. 1,269,554, 1,335,378, 1,392,192 and 2,061,116 and United States Patent Nos. 3,456,644, 3,456,645, 3,456,646, 3,565,070, 3,598,294, 3,814,297, 3,605,738, 3,732,864, 3,636,949, 3,789,843 and 3,187,748 and German Patent No. 3,040,641.

European Patent No. 147028 discloses an inhalation activatable dispenser for use with an aerosol container in which a latch mechanism releasing vane is pivotally mounted in an air passage between an aerosol outlet valve and a mouthpiece, which latch mechanism cannot be released if force to activate the dispenser is not applied before a patient inhales.

This inhalation device has been received favourably by patients and doctors since it not only overcomes the hand-lung co-ordination problem but it does so at a very low triggering flow-rate (approximately 30 litres/minute)

essentially silently, and with a very compact design barely larger than a standard inhaler.

U.S. Patent No. 4,648,393 discloses an electrically-operated metered-dose inhaler in which a mechanical valve blocking means is withdrawn by the action of a solenoid moving in response to the closing of a switch; the switch constitutes an electromechanical breath-actuation means which responds to inhalation by the patient. WO87/04354 discloses a medical dosing device for discharge of medicament for inhalation which comprises a handheld holder for a medicine container from which medicine is discharged via a valve into an air channel for inhalation by means of initiation of an activation device. The valve is operationally connected with a control unit arranged on initiation of the activation device to control the discharge valve for intermittent opening and closing repeatedly within an inhalation period. The control unit is an electronically controlled unit which activates an electrically controlled discharge valve.

In both cases the inhalation detection is achieved by electromechanical means, involving the rotation of a vane in response to inhalation and the use of this vane to close an electrical switch.

Our co-pending British Patent Application No. 9023282.8 discloses a portable inhalation device for administration of medicament in the form of aerosolised fine particles or droplets of liquid or suspension to the respiratory system of a patient, the device comprising a housing defining a chamber in communication with a patient port in the form of a mouthpiece or nasal adaptor, medicament aerosolisation means for forming an aerosol of medicament in the chamber, control means to actuate the medicament aerosolisation means and a sensor which measures the air flow rate during respiration through the patient port and provides an electrical signal to the control means which varies continuously

with said flow rate, said electrical signal being used by the control means for one or more of the following functions:

(i) to calibrate the device such that the medicament aerosolisation means is actuated at a precise, pre-determined flow rate,

(ii) to monitor one or more of the following parameters:

(a) flow rate at different times during respiration,

(b) rate of change of flow rate during respiration,

(c) respired volume during respiration, and

activate the medicament aerosolisation means when a pre-determined inspiration parameter is attained.

The device extends the use of electrical sensing in breath-actuated inhalers beyond simply detecting the presence of air flow and using that to initiate electromechanical actions. In the device the sensors continuously measure the air flow rate and the control means utilises the signals derived from the continuous measurement in a number of possible ways. Such sensors may take the form of flow sensors, e.g., those which measure the cooling effect of an air flow or those which measure the speed of rotation of a turbine in the air stream, or may incorporate pressure differential transducers, which sensors may be associated with mechanical, hydraulic, pneumatic (e.g. Pitot tubes) or other linkages to increase their sensitivity. The essential characteristic of such sensors is that they have an electrical output which varies continuously with flow rate.

The device may be of the dry powder type, pressurised aerosol type or contain other aerosol generators. The devices of the invention are portable, pocket-size, battery operated devices which may continuously accompany patients such as asthmatics who may need medication at any time.

The presence of electronics in an inhalation device increase the cost compared to a conventional press-and-breathe inhaler and many inhalation actuatable dispensers. Accordingly, it is desirable to produce an inhalation device which could be replenished with the medicament and/or be used with different medicaments. However, in the interests of patient safety such an inhalation device must be capable of being controlled or otherwise adjusted depending upon the medicament inserted into the inhalation device.

According to one aspect of the present invention there is provided an inhalation device for administration of aerosolised medicament to the respiratory system of a patient, in which the inhalation device accommodates a reservoir of medicament which comprises information relating to the medicament characterised in that the inhalation device includes sensing means capable of detecting said information and means to display or use the detected information.

The invention provides an inhalation device which can automatically read information from a medicament reservoir and use the information to control the dispensing of the medicament and/or the display of information relating to the medicament. Thus, an inhalation device of the invention may be replenished by replacing the medicament reservoir or it may be programmed to control dispensing of different medicament and/or different dosage levels of medicament.

According to a further aspect of the invention there is provided a reservoir of medicament for use with the aforesaid inhalation device, the reservoir comprising information relating to said medicament which is capable of being sensed by and either used and/or displayed by said device.

The medicament reservoir may be in the form of a pressurised aerosol container or a container holding dry powder or a solution or suspension of medicament. The container may be incorporated into a refill cartridge

which is mounted on or inserted into the body of the device. The medicament container may be arranged so as to be replenishable with additional medicament once exhausted or, alternatively, the exhausted container (or cartridge) may simply be discarded and replaced. In a further alternative, both the body of the device and the container may be discarded after use, the means of detecting information relating to the medicament only being used to ensure correct pairing of body and container during assembly. In one embodiment of the invention the medicament reservoir may be in the form of a cartridge containing an elongate carrier bearing powdered medicament as disclosed in our co-pending International Patent Application No. PCT/US90/02412.

The means of detecting the information on the reservoir of medicament may take a variety of forms, e.g.,

1. Coded electrical contacts, in the form of wipers, spring loaded contacts or pins/sockets on the medicament container (or its holder) which mate with appropriate equivalent contacts on the body of the inhaler. Such an arrangement is comparable to DX-coding in cameras which is disclosed, for example, in U.S. Patents Nos. 4,655,568 and 4,799,075.

2. Coded reflective strips on the medicament container (or its holder) which reflect light from phototransmitters on the inhaler body to photodetectors thereon. Such strips would be comparable to bar-coding.

3. A magnetic strip on the medicament container (or its holder) which holds recorded information which can be read by a magnetic reader when the container is inserted into the inhaler.

4. A coded pattern of pieces of magnetic material on the medicament container or its holder which interact with a series of reed switches on the body of the inhaler.

5. A coded series of projections on the medicament container or its holder which interact with a series of switches on the body of the inhaler. These switches may be of any suitable form, for example, they may be of push button or rocker, or paddle, or slide type, or of any combination of types. They may be of the momentary action type (each reverting to its own known default state when the refill unit is removed), or may be of sustained action type, for example, rocker switches set to the required positions by insertion of each refill unit in turn, but not reset upon removal of a refill unit. In the case of the sustained action type of switches, it may be preferable that the coded projections are on the drug container's holder and that said containers and said holders are permanently joined and that the device body is constructed such that drug containers cannot properly be inserted without a holder and that therefore an uncoded drug container (for example, a standard pressurised metered dose inhaler vial) could not be used if inserted directly into an inhaler body already programmed by previous use of a coded refill.

The information detected by the sensing means relates to the contents of the medicament container and may include one or more of the following:

1. Label claim number of doses in container.
2. Type of drug, e.g., bronchodilator, steroid, anti-allergic.
3. Strength of formulation.
4. Maximum number of doses permitted at one time.
5. Maximum dosage frequency.
6. Recommended dosage regimen.
7. Expiry date.

The inhalation device may also incorporate means to transfer information to the medicament reservoir. For example, the medicament container may be provided with a

magnetic strip and the body of the inhaler with a magnetic head which records information onto or erases it from the strip. This information may include the number of doses dispensed from and/or the number of doses remaining in the container. Alternatively, the medicament container may be provided with a non-volatile memory chip. In this manner, the partially full medicament container from a device used by a patient who has completed his or her course of treatment may be retained for re-use at a later date, but only if the number of doses remaining in the container before the label claim number of doses is reached can be precisely determined.

The inhalation device may be programmed to display the information sensed, e.g., on a liquid crystal display, and/or to use the information to control the manner in which the medicament is dispensed.

The invention will now be described with reference to the accompanying drawings in which:

Figure 1 illustrates an inhalation device in accordance with the invention,

Figure 2 illustrates the device of Figure 1 with the medicament reservoir removed,

Figures 3a, 3b and 3c represent plan, end and side views of the medicament reservoir from the inhalation device of Figure 1, and

Figure 4 illustrates another inhalation device in accordance with the invention.

Figure 1 illustrates an inhalation device in accordance with the invention comprising a body unit (2) which contains sensing means and an electronic control unit and optionally breath-sensing and breath-actuation means and electromechanical means of priming and/or firing the valve. The electronic control unit comprises a clock. The device comprises a liquid crystal display (4) which may display information concerning the

contents. The device additionally comprises a detachable refill unit (6) including a holder (8) for an aerosol container and a mouthpiece (10).

The body unit (2) shown in more detail in Figure 2 comprises an air inlet (12) and a breath-actuation sensor port (14) such that when a patient inhales through the mouthpiece (10) of the device an air flow is established through the air inlet (12), through the sensor port (14) to the mouthpiece. A breath sensor (not shown) detects the air flow and electronic control means causes movement of the valve actuation plunger (16) depressing the aerosol canister causing the aerosol valve to fire thereby dispensing medicament into the patient inhalation air flow.

The refill unit is secured to the body unit by means of a mouthpiece latch (18) and interengaging connector parts (20 and 32). When the refill unit is attached, electrical contacts (30) (Figure 3b) on the refill unit engage electrical contacts (22) on the body unit (2). The body unit (2) optionally comprises a reset switch (24) which is actuated when the refill unit is attached. The electronic system of the unit is powered by a battery mounted within the body unit (not shown).

Referring to Figures 3(a) to 3(c) the refill unit comprises a holder (8) attached to a mouthpiece (10). The holder contains an aerosol container (28) which is held in the refill unit with valve stem (36) retained in nozzle block (38). When the refill unit is attached to the body unit (2), the electrical contacts (30) engage those of the body unit and connector part (32) and latch socket (34) engage connector part (20) and the mouthpiece latch (18).

When the refill unit is inserted into the inhaler body (control unit) its coded electrical contacts mate with those on the control unit, the electronics of which detect the following information:

1. Label claim number of doses in the refill unit.

2. Maximum number of doses at one time.

3. Lock-out interval between dosing.

The label claim number of doses is then displayed by the LCD contents indicator.

When a patient takes a dose, the contents indication is reduced and the patient is allowed a short period to take a further dose (if required/appropriate) up to the maximum number of doses permitted at a single time (as determined by the coded information).

The device is then locked out for a fixed period (again as determined by the coded information) corresponding to the onset of action of the drug in use, following which the patient again has access to the defined maximum dosage.

When the label claim number of doses has been used and the contents indication has reached zero, the device will lock out, making the normal overage of contents unavailable to the patient so that the number of available doses in the refill unit can be precisely defined, and incidentally preventing dose size tail off.

Figure 4 illustrates another inhalation device in accordance with the invention for administering medicament in the dry powder form. The device comprises a body unit (40) having a mouthpiece (42) and containing sensing means (44), an electronic control unit (46), a battery (48) and an electric motor (50) capable of rotating a shaft (52) having a central air passage (54 and 56) and provided with helical blades (58). The device additionally comprises a detachable refill unit (60) comprising an inner container (62) for a compacted body of powdered medicament (64) and also a compression spring (66).

The refill unit (60) is secured to the body unit (40) by means of a latching feature (68) which interacts with socket (70). The act of latching the refill unit (60) to the body unit (40) ensures that coded pins (72)

moulded as part of the refill unit (60) engage the sensing means (44) of the body unit (40) which may, for example, take the form of a row of small rocker switches. The body unit (40) optionally comprises a spring loaded reset switch (not shown) which is actuated when the refill unit (60) is attached. The coupling of the body and refill units (40 and 60) also causes the powder compact (64) to be driven into contact with the edges of the helical blades (58) under the influence of compression spring (66).

To use the device, the patient inhales through the mouthpiece (42), thereby establishing an air flow through the air inlet (74) and via passage (54 and 56) to the mouthpiece (42). A breath sensor (not shown) detects the developing air flow and the electronic control unit (46) causes operation of the motor (50), thereby rotating shaft (52) and blades (58) a known angle, said angle being determined by the electronic control unit (46) based upon information received from the refill unit (60) via sensing means (44). A known quantity of powder (76) is thus released into the air stream for inhalation by the patient. The coded pins (72) of the refill unit (60) also provide the electronic control means (46) with information to ensure that only the label-claim number of operations of the motor (50) are permitted. A liquid crystal display (not shown) may optionally indicate the number of operations remaining.

In a further embodiment (not illustrated), the angle of rotation of the helical blades (58) is directly controlled by a ratchet arrangement on the powder container (62), the ratchet providing the information relating to the dose size of the medicament powder (64).

The features of this invention may confer the following advantages upon inhalers employing them:

1. Provision of a simple and foolproof means of ensuring that the information previously specified is registered correctly and automatically.

2. Avoidance of the need for more sophisticated means of data entry (e.g., key pad) or for any other means of entering data values which could be incorrectly set or tampered with.

3. Renders impossible the use of refill units not having appropriate coding with the control unit.

4. Facilitates means of rendering partially used refill units unusable by means of disablement of their coding upon removal of the refill. This is particularly applicable to devices employing a magnetic recording/reader, but could be applied to other embodiments also (e.g., tearing off part or all of bar coding upon removal).

5. Facilitates the setting of a precise number of available doses in the drug container.

CLAIMS

1. An inhalation device for administration of aerosolised medicament to the respiratory system of a patient, in which the inhalation device accommodates a reservoir of medicament which comprises information relating to the medicament characterised in that the inhalation device includes sensing means capable of detecting said information and means to display or use the detected information.

2. A device as claimed in Claim 1 in which the sensing means comprises electrical contacts which mate with corresponding coded electrical contacts in the form of wipers, spring loaded contacts or pins/sockets on the medicament reservoir.

3. A device as claimed in Claim 1 in which the sensing means comprises a photodetector(s) which detects light emanating from phototransmitter(s) on the body of the device and reflected from coded reflective strips on the medicament reservoir.

4. A device as claimed in Claim 1 in which the sensing means comprises a magnetic reader which reads a strip of magnetic recording material on the medicament reservoir holding said information.

5. A device as claimed in Claim 1 in which the sensing means comprises a series of reed switches which interact with a coded pattern of pieces of magnetic material on the medicament reservoir.

6. A device as claimed in Claim 1 in which the sensing means comprises a series of switches which interact with a coded series of projections on the medicament reservoir.

7. A device as claimed in any preceding Claim in which the sensing means detects at least one of the following pieces of information:

a) label claim or other number of doses in the medicament reservoir.

b) type of medicament in the reservoir.

c) strength of formulation.

d) maximum number of doses permitted at one time.

e) maximum dosage frequency.
f) lock-out interval after dosing.
g) recommended dosage regimen.
h) expiry date.

8. A device as claimed in any preceding Claim in which the device is arranged such that at least a portion of said information is destroyed or erased by removal of the reservoir from the inhalation device.

9. A device as claimed in any one of Claims 1 to 8 further comprising means to transfer information to said medicament reservoir.

10. A device as claimed in Claim 9 in which said information includes the number of doses of medicament dispensed from the reservoir and/or the number of doses of medicament remaining in the reservoir up to the label claim number of doses.

11. A device as claimed in any preceding Claim in which the device comprises means to detect patient inspiration through the mouthpiece and means to deliver medicament in response to inspiration detection.

12. A device as claimed in Claim 1 substantially as herein described with reference to the accompanying drawings.

13. A reservoir of medicament for use with an inhalation device as claimed in any one of Claims 1 to 12 characterised in that the reservoir comprises information relating to said medicament which is capable of being sensed by and either used and/or displayed by said device.

14. A reservoir as claimed in Claim 13 in which said information is encoded in one or more electrical contacts on the medicament reservoir in the form of wipers, spring loaded contacts or pins/sockets which mate with corresponding electrical contacts on the inhalation device.

15. A reservoir as claimed in Claim 13 in which said information is encoded in one or more reflective strips on the medicament reservoir which reflect light emanating

from a phototransmitter(s) on the inhalation device to a photodetector(s) thereon.

16. A reservoir as claimed in Claim 13 in which said information is encoded in one or more strips of magnetic recording material on the medicament reservoir which can be read by a magnetic recordar on the inhalation device.

17. A reservoir as claimed in Claim 13 in which said information is encoded as a pattern of pieces of magnetic material on the medicament reservoir which interact with a series of reed switches on the inhalation device.

18. A reservoir as claimed in Claim 13 in which said information is encoded in a series of projections on the medicament reservoir which interact with a series of switches on the inhalation device.

19. A reservoir as claimed in any one of Claims 13 to 18 in which said information comprises at least one of the following pieces of information:

a) label claim or other number of doses in the medicament reservoir.
b) type of medicament in the reservoir.
c) strength of formulation.
d) maximum number of doses permitted at one time.
e) maximum dosage frequency.
f) lock-out interval after dosing.
g) recommended dosage regimen.
h) expiry date.

20. A reservoir as claimed in any one of Claims 13 to 19 further comprising means to receive and store information from the inhalation device.

21. A reservoir as claimed in Claim 20 in which said information includes the number of doses of medicament dispensed from the reservoir and/or the number of doses of medicament remaining in the reservoir up to the label claim number of doses.

22. A reservoir as claimed in any one of Claims 13 to 21 in which the reservoir comprises a pressurised aerosol container.

23. A reservoir as claimed in Claim 13 substantially as herein described with reference to Figures 1, 3 and 4.

24. The combination of an inhalation device as claimed in any one of Claims 1 to 12 and a reservoir of medicament as claimed in any one of Claims 13 to 23.

25. A combination as claimed in Claim 24 substantially as herein described with reference to the accompanying drawings.

Examiner's report to the Comptroller under Section 17 (The Search Report)

Application number: 9126988.6

Relevant Technical fields	Search Examiner
(i) UK Cl (Edition X) A5T TED, TBE, TBC, TED F1R RDX	J A WALLIS
(ii) Int Cl (Edition 5) A61M	
Databases (see over)	**Date of Search**
(i) UK Patent Office	4 MARCH 1992
(ii)	

Documents considered relevant following a search in respect of claims: 1 AND 13 AT LEAST

Category (see over)	Identity of document and relevant passages	Relevant to claim(s)
X	GB 2191032 A (GLAXO) Device 1 constitutes resivoir or holder presenting 'information' line 119, page 2 - line 9, page 3	13 at least
X	GB 2063075 A (STERWIN) unit constitutes resivoir or holder displaying or recording information re-doses and/or from which data can be tapped lines 19-22, page 2	1 and 13 at least
X	GB 1383761 (WOODCRAFT) typifies medicant aerosal in inhalator	13 at least
X	GB 1362862 (LACRDAL) Aerosal bearing in contents gauge	13 at least
X	GB 1317315 (ENGLISH NUMBERING) displays doses	13 at least
X	WO 87/05813 (NILSSON) eg lines 7-14, and more particularly lines 14-22, page 7	1,13 at least
X	US 4799075 (USHIRO) whole document	1,13 at least

SF2(p)

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Category	Identity of document and relevant passages	Relevant to claim(s)

Categories of documents

X: Document indicating lack of novelty or of inventive step.

Y: Document indicating lack of inventive step if combined with one or more other documents of the same category.

A: Document indicating technological background and/or state of the art.

P: Document published on or after the declared priority date but before the filing date of the present application.

E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.

&: Member of the same patent family, corresponding document.

Databases: The UK Patent Office database comprises classified collections of GB, EP, WO and US patent specifications as outlined periodically in the Official Journal (Patents). The on-line databases considered for search are also listed periodically in the Official Journal (Patents).